

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/513,859 .	02/28/2000	D. Neale BARRET	SJO000031US1	9122	
24033 7:	590 10/18/2004		EXAM	INER	
KONRAD RAYNES & VICTOR, LLP			FRENEL,	FRENEL, VANEL	
315 S. BEVERLY DRIVE # 210		ART UNIT	PAPER NUMBER		
	BEVERLY HILLS, CA 90212				
			DATE MAILED: 10/18/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Comments	09/513,859	BARRET ET AL.				
Office Action Summary	Examiner	Art Unit				
	Vanel Frenel	3626				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 19 Ju	ly 2004.					
(a) ☐ This action is FINAL . 2b) ☐ This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	33 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1, 3-17, 19-31, 33-36 is/are pending in	the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10)☐ The drawing(s) filed on is/are: a)☐ acce	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P	ate atent Application (PTO-152)				
Paper No(s)/Mail Date	6) Other:					

DETAILED ACTION

Notice to Applicant

1. This communication is in response to Amendment filed 07/19/04. Claims 1, 5, 11, 17, 25 and 31 have been amended. Claims 2, 18 and 32 have been canceled. Claims 1, +3-17, 19-31, 33-36 are pending.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 5, 11, 17, 25, 31, 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavin et al (5,772,585) in view of Brown (6,032,119), for substantially the same reasons given in the previous Office Action. Further reasons appear hereinbelow.
- (A) Claims 1, 11, 17, 25 and 31 were apparently amended to include the word "one". However, this change does not affect the scope and the breadth as originally presented/or in the manner in which the claim were interpreted by the Examiner when applying prior art within the previous Office Action. As such, these claims are rejected under the same reason given in the prior Office Action, and incorporated herein.

The remaining features are as addressed in the previous Office Action, and Incorporated herein.

(B) Claim 5 was apparently amended to include the words "further comprising: generating log information indicating modifications to information in the patient data structure". However, Examiner respectfully submits that Brown clearly discloses this limitation in Col.6, lines 38-61).

The remaining features are as addressed in the previous Office Action, and Incorporated herein.

(C) Claims 3-4, 6-10, 12-16, 19-24, 26-30 and 33-36 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

Response to Arguments

- 4. Applicant's arguments filed 07/19/04 with respect to claims 1, 5, 11, 17, 25 and 31 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in which they appear in the response filed 07/19/04.
- (A) At pages 13-20 of the 07/19/04 response, Applicant argues the followings:
- (1) Neither Lavin nor Brown patent either alone or together teaches or suggests the subject matter of amended claims 1, 5, 11, 17, 25 and 31.
- (2) Lavin patent teaches away from generating one electronic patient data structure.
- (3) Applicant's specification defines a log as storing additions, deletions or modifications to any field or sub-record of patient information.

Application/Control Number: 09/513,859

Art Unit: 3626

(4) Lavin patent does not teach or suggest the claimed display of a main menu allowing selection of a patient bio view, a patient medication schedule view, an appointment schedule view, and a log view, wherein direct selection of one of the selectable views results in that selected view being displayed independently of the other selectable views.

Page 4

- (5) Brown patent requires selection of a log-book in order to be able to access the appointment schedule view. This teaches away fro Applicant's claimed invention.
- (6) Brown does not teach or suggest the claimed display of a main menu of selectable views, wherein the selective views comprise a patient bio-view, a medical history view, a patient medication schedule view, an appointment schedule view, and a log view.
- (7) Lavin and Brown do not teach main menu allows selection of a patient bio view, a medical history view, a patient medication schedule view, an appointment schedule view, and a log view, wherein direct selection of one of the selectable views results in that selected view being displayed independently of the other selectable views.
- (8) Viewing physician availability is not equivalent to the claimed viewing of a calendar display of a medication schedule and storing an indication that a scheduled patient medication was taken.
- (9) Lavin patent teaches away from the claimed setting of the alarm by the patient for whom the alert is scheduled and who is using the patient device.
 - (10) Lavin patent does not teach the patient file is not read-only.

- (11) The Lavin patent describes a digitized physician signature, but does not describe a physician public key.
- (12) The Lavin patent does not provide an interactive schedule of patient appointments form the appointment schedule view maintained in the patient data structures, wherein appointment events are added to one patient data structure through the displayed interactive schedule of patient appointments, and wherein the displayed interactive schedule of patient appointments displays scheduled appointments for all patient records.

The above arguments are as addressed below:

that obviousness is not determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977F. 2d 1443, 1445,24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir.1992); *In re Piaseckii*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir.1984); *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a prima facie case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (See the previous Office Action). Note, for example, in the instant case, the Examiner respectfully notes that each and every motivation to combine

the applied references are accompanied by select portions of the respective reference(s) which specially support that particular motivation and /or an explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness. As such, it is not seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one of ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood*, 28 USPQ2d 1300(Bd. Pat. App.& Inter., 4/22/93). Therefore, the combination of references is proper and the rejection is maintained.

In addition, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves.

References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, In *re Bozek*, 163 USPQ 545 (CCPA 1969). Therefore, Applicant's argument is not persuasive.

Further, it is respectfully submitted that Applicant merely provides a piecemeal analysis of the teachings of the Lavin and Brown references, separately, and in a

vacuum. As such, it is respectfully submitted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck* & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Page 7

In addition, with specific reference to Applicant's remarks about the Lavin reference, the Examiner respectfully submits that it is sufficient to demonstrate that the prior art meets the limitations as claimed, whether by a single instance or scenario, or in every possible preferred embodiment, since it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

- (i) <u>obviousness does not require absolute predictability;</u>
- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not <u>express</u> teaching of references, but what they would suggest. Therefore, Applicant's argument is not persuasive.
- (2) With respect to Applicant's second argument, Examiner respectfully submits that Brown clearly teaches an HTML page illustrating the patient's personalized health model is generated on the patient's computer by the processing means (See Brown, Col.6, lines 13-15) which correspond to Applicant's claimed feature. Therefore, Applicant's argument is not persuasive.
- (3) With respect to Applicant's third argument, Examiner respectfully submits Brown suggests "a log book (FIG. 4-D) allows the patient to access and modify records of medication, symptoms/events, lab tests, treatment plans diets, and appointment and

checkup schedules"(Col.6, lines 37-41). In addition, Brown discloses Feedback section 106 (FIG. 5A) enables the patient to record information about his or her health habits" which correspond to Applicant's claimed feature. Therefore, Applicant's argument is not persuasive.

(4) With respect to Applicant's fourth argument, Examiner respectfully submits that Brown clearly teaches "a particular user interface of a system of the present invention is illustrated in FIGS. 4 and 5. FIGS. 4-A through 4-E illustrate the functions provided by Health Avatar.TM., a diabetes management application. FIGS. 5-A through 5-G are schematic depictions of screen shots from the same application, illustrating the functions of the application. As shown in FIG. 4-A, a setup wizard is used by the patient to customize the appearance of the body image, and to enter configuration information for hardware and software in communication with the application. Hardware includes a blood glucose meter, a modem, a printer, while software includes a communications applications for communicating with health care providers and service providers. The body image itself (the Health Avatar.TM.) displays actual or simulated health information of the patient, according to actual or simulated health data (see FIG. 4-B). The patient can use a blood glucose center (FIG. 4-C) to download information from a blood glucose meter, to transfer blood glucose data to the service provider database, to transfer blood glucose data to a logbook, and to display current blood glucose levels or a history of blood glucose levels. A log book (FIG. 4-D) allows the patient to access and modify records of medication, symptoms/events, lab tests, treatment plans, diets, and

appointment and checkup schedules. A mail center (FIG. 4-E) is used by the patient to download treatment directions from the health provider, to transfer log book contents to the service provider and/or the health provider, and to communicate by-e-mail with the health provider. FIG. 5-A is a schematic depiction of a screen shot 90 of the Health Avatar.TM. application. The display comprises several sections: a body image section 100, a log book section 102, a blood glucose center section 104, a feedback section 106, and a mail center section 108. The patient accesses functions of the application by clicking on corresponding display sections or subsections. The functions of the log book module become accessible if the patient clicks on log book section 102, as illustrated in FIG. 5-B. A similar display (not shown) is generated if the patient clicks on blood glucose center section 104. FIG. 5-C illustrates the display after the patient accesses the "Display Blood Glucose Level" (see FIG. 4-C) subfunction of the blood glucose center. Feedback section 106 (FIG. 5A) enables the patient to record information about his or her health habits" which correspond to Applicant's claimed feature (See Brown, Col.6, lines 16-61). Therefore, Applicant's argument is not persuasive.

5. With respect to Applicant's fifth argument, Examiner respectfully submits Brown suggests "a log book (FIG. 4-D) allows the patient to access and modify records of medication, symptoms/events, lab tests, treatment plans diets, and appointment and checkup schedules" (Col.6, lines 37-41). In addition, Brown discloses Feedback section 106 (FIG. 5A) enables the patient to record information about his or her health habits" which correspond to Applicant's claimed feature. Therefore, Applicant's argument is not persuasive.

(6) & 7With respect to Applicant's sixth and seventh arguments, Examiner respectfully submits Brown clearly teaches "a particular user interface of a system of the present invention is illustrated in FIGS. 4 and 5. FIGS. 4-A through 4-E illustrate the functions provided by Health Avatar.TM., a diabetes management application. FIGS. 5-A through 5-G are schematic depictions of screen shots from the same application, illustrating the functions of the application. As shown in FIG. 4-A, a setup wizard is used by the patient to customize the appearance of the body image, and to enter configuration information for hardware and software in communication with the application. Hardware includes a blood glucose meter, a modem, a printer, while software includes a communications applications for communicating with health care providers and service providers. The body image itself (the Health Avatar.TM.) displays actual or simulated health information of the patient, according to actual or simulated health data (see FIG. 4-B). The patient can use a blood glucose center (FIG. 4-C) to download information from a blood glucose meter, to transfer blood glucose data to the service provider database, to transfer blood glucose data to a logbook, and to display current blood glucose levels or a history of blood glucose levels. A log book (FIG. 4-D) allows the patient to access and modify records of medication, symptoms/events, lab tests, treatment plans, diets, and appointment and checkup schedules. A mail center (FIG. 4-E) is used by the patient to download treatment directions from the health provider, to transfer log book contents to the service provider and/or the health provider, and to communicate by-e-mail with the health provider. FIG. 5-A is a schematic depiction of a screen shot 90 of the Health Avatar.TM. application. The display comprises several sections: a body image section

Page 11

100, a log book section 102, a blood glucose center section 104, a feedback section 106, and a mail center section 108. The patient accesses functions of the application by clicking on corresponding display sections or subsections. The functions of the log book module become accessible if the patient clicks on log book section 102, as illustrated in FIG. 5-B. A similar display (not shown) is generated if the patient clicks on blood glucose center section 104. FIG. 5-C illustrates the display after the patient accesses the "Display Blood Glucose Level" (see FIG. 4-C) subfunction of the blood glucose center. Feedback section 106 (FIG. 5A) enables the patient to record information about his or her health habits" which correspond to Applicant's claimed feature (See Brown, Col.6, lines 16-61). Therefore, Applicant's argument is not persuasive.

(8)With respect to Applicant's eighth argument, Examiner respectfully submits Brown clearly teaches "the multimedia processor connects the processing means on the central server to inputs located at the patient's home: a patient feedback means preferably comprising a keyboard, and a patient identification means preferably comprising a data-bearing card, or "smart card". The multimedia processor has a receiving slot for receiving the patient identification smart card. The patient identification card contains an encrypted patient code, a prescribed treatment for the patient, and a URL address of the processing means. The keyboard allows the patient to provide a subset of feedback data, including display preferences specifying a formatting of the display. The set of inputs further comprises inputs located at a health care provider location, including records of: a medical history of the patient, a standard of care for a

general health condition or disease of the patient, a prescribed treatment for the patient, and a personal profile of the patient. The above-incorporated U.S. patent application Ser. No. 08/732,158 entitled "Multiple Patient Monitoring System for Proactive Health Management" contains further information on data available to the health care provider. Examples of data specified by the inputs include blood glucose level histories, generally acceptable blood glucose levels, dates of doctor examinations, generally recommended time periods between doctor examinations, ratings of the patient's interest for a cultural subject (e.g. sports, music), and display customization variables entered by the patient' which correspond to Applicant's claimed feature (See Brown, Col.20-48). Therefore, Applicant's argument is not persuasive.

(9) With respect to Applicant's ninth argument, Examiner respectfully submits Brown clearly teaches "The body image itself (the Health Avatar.TM.) displays actual or simulated health information of the patient, according to actual or simulated health data (see FIG. 4-B). The patient can use a blood glucose center (FIG. 4-C) to download information from a blood glucose meter, to transfer blood glucose data to the service provider database, to transfer blood glucose data to a logbook, and to display current blood glucose levels or a history of blood glucose levels. A log book (FIG. 4-D) allows the patient to access and modify records of medication, symptoms/events, lab tests, treatment plans, diets, and appointment and checkup schedules. A mail center (FIG. 4-E) is used by the patient to download treatment directions from the health provider, to transfer log book contents to the service provider and/or the health provider, and to

Application/Control Number: 09/513,859

Art Unit: 3626

communicate by-e-mail with the health provider" which corresponds to Applicant's claimed feature (See Brown, Col.6, lines 30-45). Therefore, Applicant's argument is not persuasive.

Page 13

With respect to Applicant's tenth argument, Examiner respectfully submits Lavin (10)clearly teaches "A presently preferred embodiment is typically operated in a medical clinic environment where medical practitioners and staff require access to various types of information previously recorded about existing patients and also require the ability to add new patients to the clinic's files. Every user of the system 10 enters a user name and a password to access information as a security measure, and different levels of data access can be granted to different users. The information relating to the security measures is stored in the relational database in a User Information table, or namely "User.sub. Infor" table 374 (in FIG. 21). As shown in FIG. 2, when a user first accesses the system, a main menu display 28 will present the user with several options. The user selects the desired task through the data entry device 26. The main menu display includes an appointment button 30, a patient information button 32, a clinical button 34, a reports button 36 and a utilities button 38. Each of these command buttons permits the user to enter a specific group of data entry and retrieval screens for managing and processing patient information" which correspond to Applicant's claimed feature (See Lavin, Col.5, lines 36-56). Therefore, Applicant's argument is not persuasive.

- (11) With respect to Applicant's eleventh argument regarding a physician public key, Examiner looked everywhere in the claims for such a feature but couldn't find it.

 However, Applicant's has been discussed a limitation which is not in the recited claims.

 Therefore, Applicant's argument is not persuasive.
- (12) With respect to Applicant's tenth argument, Examiner respectfully submits Lavin clearly teaches "The data contained in the database described above, preferably within the tables shown in FIGS. 21-24, can allow the user to access and analyze patient data in a variety of ways. In particular, the information previously gathered and stored in the database can be analyzed or compiled to track the effectiveness of treatments or medications on particular illnesses and the reasons therefor. Furthermore, patterns of diseases or symptoms may be tracked within a given geographical area or group of patients. The user can also identify trends in patient load and schedule in order to maximize the efficiency and effective use of the physician's time. These various analyses may be accomplished via user screens similar to those described previously. For example, the user can choose an item (such as a table or a group of tables) and "drag" the item to a place on the screen and "drop" the item onto various icons representing processing options. The program would determine the hierarchy of the data chosen and group the data to generate data queries. The compiled data could then be printed into report format for use outside of the system. From the foregoing, a comprehensive system and method for managing patient medical information in a medical clinic or physician's office has been described. The system includes at least a

computer having a processor, memory, data input device and display capable of receiving, manipulating and displaying medical information. A common graphic user interface allows authorized users to manage medical information and provides physicians with a useful diagnostic tool to assist in examination and diagnosis of patients. Additionally, a method of managing, storing, recording and displaying patient medical data has been described that includes scheduling appointments, obtaining patient background information, retrieving, recording and displaying patient examination information, generating billing materials, generating analysis reports and generating prescriptions" which correspond to Applicant's claimed feature (See Lavin, Col.47-67 to Col.16, line 16). Therefore, Applicant's argument is not persuasive.

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Application/Control Number: 09/513,859 Page 16

Art Unit: 3626

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on Monday-Thursday form 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F V.F

September 29, 2004

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
SUPERVISORY CENTER 3600